REMARKS

I. Introduction

Claims 11 to 25 are pending in the present application. In view of the foregoing amendments and the following remarks, it is respectfully submitted that all of the presently pending claims are allowable, and reconsideration is respectfully requested.

II. Objection to Claim 11

Claim 11 was objected to because it recited, at line 6, "the dilution device" which lacks antecedent basis. As suggested by the Examiner, Applicant has amended claim 11 to instead recite "the diluting device". Therefore, Applicant respectfully requests that this objection be withdrawn.

III. Rejection of Claims 11 to 13 and 20 to 22 Under 35 U.S.C. § 102(b)

Claims 11 to 13 and 20 to 22 were rejected under 35 U.S.C. 102(b) as anticipated by U.S. Patent No. 3,655,123 ("Judson et al."). Applicant respectfully submits that Judson et al. do not anticipate the present claims for the following reasons.

Claim 11 relates to a device for processing cell suspensions for autotransfusion. Claim 11 recites that the device includes at least one separation unit for separating cells by centrifugation. Claim 11 also recites that the separation unit comprises a suspension inlet line and a concentrated cell outlet line having a concentrated cell outlet pump under the control of a controller, and a waste line each located downstream of the suspension inlet line. Claim 11 also recites that the concentrated cell outlet line is connected to a diluting device, the dilution device being in fluid connection with the concentrated cell outlet line via a solution line for delivering physiologic solution. Claim 11 has been amended without prejudice herein to recite that the solution line is connected to the concentrated cell outlet line upstream of the concentrated cell outlet pump. Support for this amendment can be found, for instance, at page 7, lines 6 to 10 of the Specification which states "[d]ilution device 22 includes a tank 15 to hold the dilution solution ... with an inlet line 16 leading away from it and opening into the first outlet line 9 upstream from concentrate pump 11 at a mixing point 23." Emphasis added. Claim 11 recites that

cells contained in a suspension entering the separation unit through the inlet line under the control of the controller are concentrated in the separation unit, removed through the concentrated cell outlet line, and diluted via the diluting device with a physiologic solution.

Judson et al. purport to disclose a continuous flow blood separator, and in particular an apparatus for separating whole blood into at least two fractional components and continuously returning at least one component to the source of the blood. Abstract. The Office Action states that "Judson et al[.] teach a blood centrifugation device comprising a centrifuge (52) having a blood suspension inlet (90), a waste line and a concentrated cell outlet line with a concentrated cell pump (66) and a diluting device (76) in fluid connection with the concentrated cell outlet line via plasma outlet line from centrifuge (52) for delivering plasma e.g. physiologic solution via plasma pump (70) wherein plasma combines with the concentrated red blood cells to inherently dilute concentrated red blood cells because plasma is of lighter fluid than red blood cells (see figure 1; col. 7, line 29- col. 10, line 57)." Office Action at page 2. The Office Action also states that "[b]lood suspension inlet line is controlled by a blood pump (62) (see col. 20, lines 29-38; col. 21, lines 36-68) ... [and] concentrated red blood cell pump (66) is controlled by red blood cell pump control (706) (see figure 18; col. 27, lines 12-23)." Office Action at page 2.

It is respectfully submitted that Judson et al. do not anticipate amended claim 11 for at least the reason that Judson et al. do not disclose, or even suggest, all of the features recited in amended claim 11. For example, Judson et al. fail to disclose, or even suggest, a dilution device being in fluid connection with a concentrated cell outlet line via a solution line for delivering physiologic solution, wherein the solution line is connected to the concentrated cell outlet line upstream of the concentrated cell outlet pump, as recited in amended claim 11. Rather, Judson et al. describe and illustrate in Figure 1 that the needle rinse mechanism 72 is connected downstream of the red cell pump 66.

To anticipate a claim, each and every element as set forth in the claim must be found in a single prior art reference. Verdegaal Bros. v. Union Oil Co. of Calif., 814 F.2d 628, 631, 2 U.S.P.Q.2d 1051, 1053 (Fed. Cir. 1987). Furthermore, "[t]he identical invention must be shown in as complete detail as is contained in the . . . claim." Richardson v. Suzuki Motor Co., 868 F.2d 1226, 1236, 9 U.S.P.Q.2d 1913, 1920 (Fed. Cir. 1989). That is, the prior art must describe the elements

arranged as required by the claims. In re Bond, 910 F.2d 831, 15 U.S.P.Q.2d 1566 (Fed. Cir. 1990). As more fully set forth above, it is respectfully submitted that Judson et al. do not disclose, or even suggest, all of the features recited in amended claim 11, because Judson et al. do not disclose, or even suggest, a dilution device being in fluid connection with a concentrated cell outlet line via a solution line for delivering physiologic solution, wherein the solution line is connected to the concentrated cell outlet line upstream of the concentrated cell outlet pump, as recited in amended claim 11.

Additionally, to reject a claim under 35 U.S.C. § 102, the Examiner must demonstrate that each and every claim limitation is contained in a single prior art reference. See, Scripps Clinic & Research Foundation v. Genentech, Inc., 18 U.S.P.Q.2d 1001, 1010 (Fed. Cir. 1991). Still further, not only must each of the claim limitations be identically disclosed, an anticipatory reference must also enable a person having ordinary skill in the art to practice the claimed invention, namely the inventions of the rejected claims, as discussed above. See, Akzo, N.V. v. U.S.I.T.C., 1 U.S.P.Q.2d 1241, 1245 (Fed. Cir. 1986). In particular, it is respectfully submitted that, at least for the reasons discussed above, the reference relied upon would not enable a person having ordinary skill in the art to practice the inventions of the rejected claims, as discussed above. Also, to the extent that the Examiner is relying on the doctrine of inherency, the Examiner must provide a "basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristics necessarily flows from the teachings of the applied art." See M.P.E.P. § 2112; emphasis in original; and see, Ex parte Levy, 17 U.S.P.Q.2d 1461, 1464 (Bd. Pat. App. & Inter. 1990). Thus, the M.P.E.P. and the case law make clear that simply because a certain result or characteristic may occur in the prior art does not establish the inherency of that result or characteristic. Accordingly, the anticipation rejection as to the rejected claims must necessarily fail for the foregoing reasons.

In summary, it is respectfully submitted that Judson et al. do not anticipate amended claim 11.

As for claims 12, 13 and 20 to 22, which ultimately depend from amended claim 11 and therefore include all of the limitations of amended claim 11, it is respectfully submitted that Judson et al. do not anticipate these dependent claims

for at least the same reasons given above in support of the patentability of amended claim 11.

IV. Rejection of Claim 19 Under 35 U.S.C. § 103(a)

Claim 19 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Judson et al. It is respectfully submitted that Judson et al. do not render obvious the present claims as amended herein for the following reasons.

With respect to claim 19, the Office Action contends that"Judson et al. teach a separation unit having separation channels (see figures 5-11; col. 14, line 10 - col. 17, line 52)." Office Action at page 3. The Office Action contends that"[c]laim 19 essentially differs from the apparatus of Judson et al. in reciting that the separation unit has a shape selected from the group consisting of a ring or a spiral." Office Action at page 3. The Office Action concludes that "[i]t would have been an obvious matter of design choice to modify the separation unit in a shape of ring or spiral, since applicant has not disclosed that the separation unit in a shape of ring or spiral solves any stated problem or is for any particular purpose and it appears that the invention would perform equally well with any other shape such as square or diamond or bowl." Office Action at page 3.

It is respectfully submitted that Judson et al. do not disclose, or even suggest, all of the limitations recited in claim 19. For instance, claim 19 depends from amended claim 11 and therefore includes all of the limitations of amended claim 11. As stated above, Judson et al. do not disclose, or even suggest, a dilution device being in fluid connection with a concentrated cell outlet line via a solution line for delivering physiologic solution, wherein the solution line is connected to the concentrated cell outlet line upstream of the concentrated cell outlet pump, as recited in amended claim 11.

In rejecting a claim under 35 U.S.C. § 103(a), the Examiner bears the initial burden of presenting a prima facie case of obviousness. In re Rijckaert, 9 F.3d 1531, 1532, 28 U.S.P.Q.2d 1955, 1956 (Fed. Cir. 1993). To establish prima facie obviousness, three criteria must be satisfied. First, there must be some suggestion or motivation to modify or combine reference teachings. In re Fine, 837 F.2d 1071, 5 U.S.P.Q.2d 1596 (Fed. Cir. 1988). This teaching or suggestion to make the claimed combination must be found in the prior art and not based on the application disclosure. In re Vaeck, 947 F.2d 488, 20 U.S.P.Q.2d 1438 (Fed. Cir.

1991). Second, there must be a reasonable expectation of success. In re Merck & Co., Inc., 800 F.2d 1091, 231 U.S.P.Q. 375 (Fed. Cir. 1986). Third, the prior art reference(s) must teach or suggest all of the claim limitations. In re Royka, 490 F.2d 981, 180 U.S.P.Q. 580 (C.C.P.A. 1974). As indicated above, Judson et al. do not disclose, or even suggest, all of the limitations recited in claim 19, because Judson et al. do not disclose, or even suggest, a dilution device being in fluid connection with a concentrated cell outlet line via a solution line for delivering physiologic solution, wherein the solution line is connected to the concentrated cell outlet line upstream of the concentrated cell outlet pump, as recited in amended claim 11, from which claim 19 depends. It is therefore respectfully submitted that Judson et al. do not render obvious claim 19.

Accordingly, there is no evidence that the references relied upon, whether taken alone or modified, would provide the features and benefits of claim 19. It is therefore respectfully submitted that claim 19 is allowable for these reasons.

V. Allowable Subject Matter

Applicants note with appreciation the indication that claims 14 to 18 and 23 to 25 are allowed.

VI. Conclusion

It is therefore respectfully submitted that all of the presently pending claims are allowable. All issues raised by the Examiner having been addressed, an early and favorable action on the merits is earnestly solicited.

Respectfully submitted,

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